REMARKS

Applicants submit the Amendment in response to the Office Action mailed June 28, 2004. Claims 1-56 are withdrawn, and previously pending claims 57-62 are cancelled herein, in favor of newly presented claims 63-76, which are supported in the specification as discussed below.

Applicants thank the Examiner for the courtesy of the telephone interview held on September 1, 2004, and acknowledge the Interview Summary dated September 15, 2004. The region of SEQ ID NO:74 having homology to the Norrie disease gene is clarified and discussed further, below, in response to the rejection under 35 U.S.C. § 101.

Claims 57-62 are provisionally rejected over claims 8-13 and 28 of copending application Serial No. 10/355,716. As this is a provisional double patenting rejection, applicants request that the Examiner hold it in abeyance pending notification of allowable subject matter in either application.

Claims 57-62 stand rejected under 35 U.S.C. § 101 because the claimed invention allegedly lacks patentable utility. At page 3 of the Office Action mailed June 28, 2004, the Examiner states that the argument presented in the response filed December 23, 2003 is unconvincing for two reasons: 1) the gene disclosed by Chen et al. (Nature Genetics 1(3):204-208 (1992)) is not described definitively as being the gene that causes Norrie disease, but rather as a candidate gene for that disease, and 2) one skilled in the art would not have considered SEQ ID NO:74 as encoding the Norrie gene. Reconsideration and withdrawal of this rejection are respectfully requested.

Regarding reason 1, Applicants draw the Examiner's attention to more recently published scientific literature which has removed any uncertainty about the association of the gene disclosed by Chen et al. (1992) and Norrie disease. Kim et al. (Korean J. Opthalmol. 16(2):93-96 (2002)) and Strausberg et al. (Proc. Natl. Acad. Sci. U.S.A. 99(26):16899-16903 (2002)) each disclose a human nucleotide sequence containing the gene specifically defined as being the Norrie disease gene (GenBank Accession Nos. NM_000266 and BC029901, respectively). Tests using the BLASTN nucleotide sequence alignment algorithm (Version 2.2.9) demonstrate sequence identities of 100% and 99% for NM_000266 and BC029901, respectively, with the

nucleotide sequence disclosed by Chen et al. (1992) (GenBank Accession No. X65882). Alignments are submitted herewith as Exhibits 1 and 2.

Regarding reason 2, Applicants agree with the Examiner that SEQ ID NO: 74 could not encode the full Norrie disease-associated polypeptide. However, Applicants reiterate their contention, presented on pages 3 and 4 of the amendment filed on March 18, 2002, that SEQ ID NO:74 contains significant nucleotide sequence homology with the Norrie disease gene. A test using the BLASTN nucleotide sequence alignment algorithm (Version 2.2.9) demonstrates a sequence identity of 88% between SEQ ID NO:74 and the human Norrie disease gene sequence disclosed by Chen et al. (1992) (GenBank Accession No. X65882). On page 16, lines 12-36 of the specification, the utility of polynucleotides of 50, 90 and 150 nucleotides in length is described: such polynucleotides "... are generally sufficient for unique identification of specific location in genomic DNA of a sequence coding for an unique protein. Furthermore, a 50-base pair sequence is long enough to design a PCR primer from the sequence to amplify the complete polynucleotides," (lines 31-36). Base pair numbers 1-155 of SEQ ID NO:74 contain this 88% identity with the Norrie disease gene and, with this amendment, they are now specified in the newly-submitted claims 63-76. These claims are clearly supported as discussed above.

In the Office Action mailed June 28, 2004, citing reasons discussed in the Office Action of June 4, 2002, page 2, the Examiner has also rejected claims 57-62 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. With the Supplemental Information Disclosure Statement accompanying this Amendment, Chen et al. (1992) is now part of the record. Also entered in the record are Kim et al. (2002) and Strausberg et al. (2002), which are cited above as supporting evidence that the nucleotide sequence described in Chen et al. (1992) is in fact the Norrie disease gene. The third, fourth and fifth reasons the for lack of enablement rejection cited by the Examiner on page 2 of the June 4, 2002 Office Action are now obviated by this Amendment: 3) the sequence alignment of SEQ ID NO:74 and the Norrie disease gene is now in the record; 4) as explained in the immediately preceding paragraph, lines 12-36 of page 16 of the specification describe the use of SEQ ID NO:74; and 5) withdrawal of all claims pertaining to Norrie disease-specific polypeptide make moot this ground of rejection.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

Respectfully submitted,
Max Cynader et al.
DAVIS WRIGHT TREMAINE LLP

By _____
Jane E. R. Potter
Registration No. 33,332

2600 Century Square
1501 Fourth Avenue
Seattle, WA 98101-1688
Phone: (206) 628-7650
Facsimile: (206) 628-7699

BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.9 [May-01-2004]

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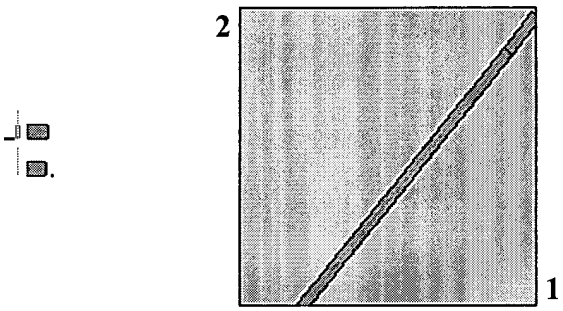
Sequence 2 gi 20987431 Strausberg et al. - Homo sapiens Norrie disease (pseudoglioma), mRNA **Length** 1495 (1 .. 1495)

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Norrie disease protein 116    L  T  A  T  Y  R  Y  I  L  S  C  H  C  E  E  C  N  S  ^^^

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Gapped
Lambda K H
1.33 0.621 1.12

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Gap Penalties: Existence: 5, Extension: 2
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Number of successful extensions: 50
Number of sequences better than 10.0: 1
Number of HSP's better than 10.0 without gapping: 1
Number of HSP's gapped: 32
Number of HSP's successfully gapped: 2
Number of extra gapped extensions for HSPs above 10.0: 0
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Length adjustment: 26
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BLAST 2 SEQUENCES RESULTS VERSION BLASTN 2.2.9 [May-01-2004]

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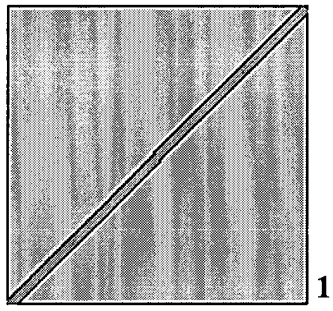


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Norrie disease protein    1                                                   M  R  K  H


Seq 1:                    421  gtactagctgcatccttttctatgctctccctgctggtgataatgggagatacagacagt 480
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Seq 1:                    481  aaaacggacagctcattcataatggactcggaccctcgacgctgcatgaggcaccactat 540
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Seq 1:                    541  gtggattctatcagtcacccattgtacaagtgtagctcaaagatggtgctcctggccagg 600
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Seq 1:                    601  tgcgaggggcactgcagccaggcgtcacgctccgagcctttggtgtcgttcagcactgtc 660
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Norrie disease protein    65    C  E  G  H  C  S  Q  A  S  R  S  E  P  L  V  S  F  S  T  V


Seq 1:                    661  ctcaagcaacccttccgttcctcctgtcactgctgccggccccagacttccaagctgaag 720
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Seq 1:                    721  gcactgcggctgcgatgctcaggggcatgcgactcactgccacctaccggtacatcctc 780
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Seq 2:                    721  gcactgcggctgcgatgctcaggggcatgcgactcactgccacctaccggtacatcctc 780
Norrie disease protein    105   A  L  R  L  R  C  S  G  G  M  R  L  T  A  T  Y  R  Y  I  L


Seq 1:                    781  tcctgtcactgcgaggaatgcaattcctgaggcccgctgctgtgtgtggcttctggatgg 840
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Seq 2:                    781  tcctgtcactgcgaggaatgcaattcctgaggcccgctgctgtgtgtggcttctggatgg 840
Norrie disease protein    125   S  C  H  C  E  E  C  N  S  ^^^


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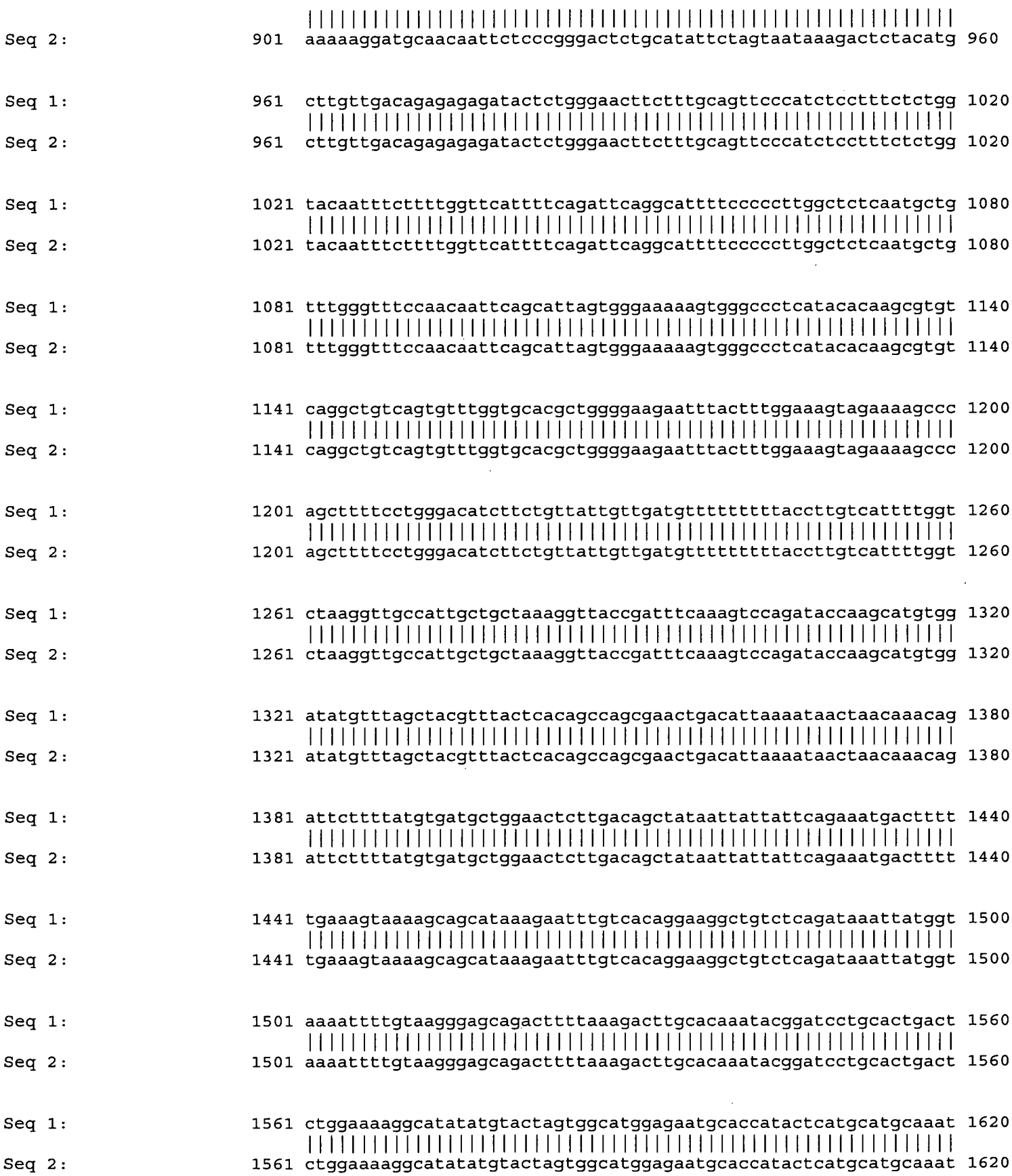
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Seq 2: 1261 ctaaggttgccattgctgctaaaggttaccgatttcaaagtccagataccaagcatgtgg 1320
Seq 1: 1321 atatgtttagctacgtttactcacagccagcgaactgacattaaaataactaacaaacag 1380
Seq 2: 1321 atatgtttagctacgtttactcacagccagcgaactgacattaaaataactaacaaacag 1380
Seq 1: 1381 attcttttatgtgatgctggaactcttgacagctataattattattcagaaatgactttt 1440
Seq 2: 1381 attcttttatgtgatgctggaactcttgacagctataattattattcagaaatgactttt 1440
Seq 1: 1441 tgaaagtaaaagcagcataaagaatttgtcacaggaaggctgtctcagataaattatggt 1500
Seq 2: 1441 tgaaagtaaaagcagcataaagaatttgtcacaggaaggctgtctcagataaattatggt 1500
Seq 1: 1501 aaaattttgtaagggagcagacttttaaagacttgcacaaatacggatcctgcactgact 1560
Seq 2: 1501 aaaattttgtaagggagcagacttttaaagacttgcacaaatacggatcctgcactgact 1560
Seq 1: 1561 ctggaaaaggcatatatgtactagtggcatggagaatgcaccatactcatgcatgcaaat 1620
Seq 2: 1561 ctggaaaaggcatatatgtactagtggcatggagaatgcaccatactcatgcatgcaaat 1620

```
Seq 1:                1621 tagacaaccaagtatgaatctatttgtgggtgtgctatagctttagcgtgtcacgggcat 1680
                           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Seq 2:                1621 tagacaaccaagtatgaatctatttgtgggtgtgctatagctttagcgtgtcacgggcat 1680


Seq 1:                1681 cattctctaatatccacttgtccatgtgaaacatgttgccaaaatggtggcctggcttgt 1740
                           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Seq 2:                1681 cattctctaatatccacttgtccatgtgaaacatgttgccaaaatggtggcctggcttgt 1740


Seq 1:                1741 cttctgaacgtttggttcaaatgtgttttggtcctggaggctcaaattttgagttattcc 1800
                           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Seq 2:                1741 cttctgaacgtttggttcaaatgtgttttggtcctggaggctcaaattttgagttattcc 1800


Seq 1:                1801 cacgttttgaaataaaaagagtatattcaaaaaaaaaaaaaaaaaa 1846
                           ||||||||||||||||||||||||||||||||||||||||||
Seq 2:                1801 cacgttttgaaataaaaagagtatattcaaaaaaaaaaaaaaaaaa 1846
CPU time:     0.02 user secs.      0.01 sys. secs         0.03 total secs.

Lambda     K      H
    1.33    0.621     1.12

Gapped
Lambda     K      H
    1.33    0.621     1.12


Matrix: blastn matrix:1 -2
Gap Penalties: Existence: 5, Extension: 2
Number of Sequences: 1
Number of Hits to DB: 578
Number of extensions: 31
Number of successful extensions: 17
Number of sequences better than 10.0: 1
Number of HSP's better than 10.0 without gapping: 1
Number of HSP's gapped: 1
Number of HSP's successfully gapped: 1
Number of extra gapped extensions for HSPs above 10.0: 0
Length of Seq 1: 1846
Length of database: 11,840,914,473
Length adjustment: 26
Effective length of Seq 1: 1820
Effective length of database: 11,840,914,447
Effective search space: 21550464293540
Effective search space used: 21550464293540
Neighboring words threshold: 0
Window for multiple hits: 0
X1: 11 (21.1 bits)
X2: 26 (50.0 bits)
X3: 26 (50.0 bits)
S1: 12 (25.0 bits)
S2: 21 (41.1 bits)
```